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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LIN, JERRY

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/881,748	Applicant(s) SHIOTA ET AL.	
	Examiner Jerry Lin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,8,9 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,8,9 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed February 16, 2006, have been fully considered and they are to be persuasive. Therefore, the finality of that action is withdrawn. The following rejections and/or objections are newly applied in light of newly discovered prior art. They constitute the complete set presently being applied to the instant application.

Currently, claims 6, 8, 9, and 19-23 are under examination.

The applicant has canceled claims 1-5, 7 and 10-18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 8, 9, and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olek et al. (US 6,214,556 B1) in view of Ohgane et al. (Development Genetics Volume 22, pages 132-140) further in view of Labosky et al. (Development (1994) Volume 120, pages 3197-3204).

The instant claims are drawn to a method of identifying the differentiation state of a stem cell by comparing the methylation pattern of a stem cell to the methylation pattern of a cell of a known differentiation state.

Regarding claim 8, Olek et al. teaches a generic method of identifying cells types as well as cell states or stages through the use of methylation fingerprint patterns (column 14, lines 50-58; column 17, lines 30-40; column 2, lines 35-44; column 24-25). In his method he teaches obtaining a DNA methylation pattern for a test cell (columns 24-25); obtaining a reference pattern for a particular cell type (columns 24-25); comparing the test cell DNA methylation pattern with the reference pattern (columns 24-25); and matching the test cell DNA methylation pattern with a reference pattern to determine the cell type (columns 24-25).

However, Olek et al. do not specifically teach using a reference pattern for differentiation states to determine the differentiation state of a stem cell. In other words, Olek et al. teach the generic version of the instant claims where a practitioner may use their method to determine any cell type or stage, but Olek et al. do not teach the instant claims as they are specifically applied to differentiation states.

Also regarding claim 8, Ohgane et al. provide "differentiation state-specific DNA methylation patterns" that distinguished the placenta from kidney (page 134, right

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column, bottom paragraph – page 136). Specifically, Ohgane et al. compare the DNA methylation patterns and find that the spots in Group II are found in the placenta but not in the kidney. They also find that the spots in Group IV are found in the kidney but not in the placenta. Using the DNA methylation patterns of this description, a practitioner may distinguish between tissue from the placenta and the kidney. Thus the DNA methylation patterns in Ohgane et al. are differentiation state-specific.

Also regarding claims 8, 19, 21 and 22, Labosky et al. provide the methylation patterns of embryonic germ cell lines (undifferentiated cells), embryonic stem cell lines, and compare the patterns of methylation of the embryonic germ cell lines and the embryonic stem cell lines (page 3200-3201)

Given that Olek et al. provide a method of identifying cell types using DNA methylation patterns, Ohgane et al. provide DNA methylation patterns specific to differentiation states, and Labosky et al. provide methylation patterns of stem cells, the combination of the methods would create a method of identifying differentiation states using DNA methylation patterns specific to differentiation states. Thus the combination of the two teaches the limitation of instant claim 8.

Regarding claim 6 and 9, Ohgane et al. teach in the abstract and throughout, especially in Figure 1 and Tables 1-3, a comparison of methylation patterns at 2900 sites of polyploidy rat trophoblast giant cell DNA with that of diploid labyrinth zone and maternal kidney cells by use of the RLGS method. Four regions were sequenced to analyze the sequence of CpG island in the methylated regions.

Regarding claims 20, 22, and 23, Ohgane et al. teach obtaining DNA methylation patterns for the kidney or placenta (a differentiated cell) (page 134, right column, bottom paragraph – page 136) and generating DNA methylation patterns with RLGS profiles (Figure 1 and Tables 1-3).

One of ordinary skill in the art at the time the invention was made would have combined the methods of Olek et al. with Ohgane et al. and Labosky et al. to create a method of identifying unknown cell samples. Olek et al. teaches a generic method of identifying cell types through DNA methylation patterns. However in order to use Olek et al.'s method, one of ordinary skill in the art would have to find reference methylation patterns to which a sample methylation pattern can be compared. Ohgane et al. and Labosky et al. provide such DNA methylation patterns. Thus one of ordinary skill in the art would be motivated to take the DNA methylation pattern from Ohgane et al. and incorporate it into Olek et al.'s method in order to identify unknown cell samples.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

JL

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

